

**US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
FISCAL YEAR 2017 (FY17) BREAST CANCER RESEARCH PROGRAM (BCRP)**

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY17 BCRP called for applications in response to program announcements (PAs) for four award mechanisms released in August 2017:

- Era of Hope Scholar Award
- Breakthrough Award Levels 3 and 4
- Innovator Award
- Distinguished Investigator Award

In response to the Era of Hope Scholar Award PA, eight compliant applications were received in December 2017 and peer reviewed in February 2018. Stage 1 programmatic review was conducted in April 2018, and none were invited to Stage 2 programmatic review (oral presentation).

Pre-applications were received for the Breakthrough Award Levels 3 and 4, Innovator Award, and Distinguished Investigator Award PAs in September 2017 and screened in October 2017 to determine which investigators would be invited to submit a full application. Pre-applications were screened based on the evaluation criteria specified in the PAs.

Applications were received for these PAs in December 2017 and peer reviewed in February 2018. Programmatic review was conducted in April 2018.

In response to the Breakthrough Award Levels 3 and 4 PA, 46 pre-applications were received for Funding Level 3. The Principal Investigators (PIs) of 13 pre-applications were invited to submit a full application. Thirteen compliant applications were received, and one (7.7%) was recommended for funding.

In response to the Breakthrough Award Levels 3 and 4 PA, 7 pre-applications were received for Funding Level 4. The PIs of 3 pre-applications were invited to submit a full application. Two compliant applications were received, and none were recommended for invitation to Stage 2 programmatic review (oral presentation).

In response to the Innovator Award PA, 17 pre-applications were received. The PIs of three pre-applications were invited to submit a full application. Two compliant applications were received, and none were recommended for invitation to Stage 2 programmatic review (oral presentation).

In response to the Distinguished Investigator Award PA, nine pre-applications were received. The PIs of one pre-application was invited to submit a full application. One compliant application was received, and one was recommended for invitation to Stage 2 programmatic review (oral presentation).

Submission and award data for the FY17 BCRP Breakthrough Award Levels 3 and 4, Era of Hope Scholar Award, Innovator Award, and Distinguished Investigator Award are summarized in the tables below.

Table 1. Submission/Award Data for the FY17 BCRP*

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Breakthrough Award – Funding Level 3	46	13 (28.3%)	13	1 (7.7%)	\$6,756,270
Total	46	13 (28.3%)	13	1 (7.7%)	\$6,756,270

*These data reflect funding recommendations only. Pending FY17 award negotiations, final numbers will be available after September 30, 2018.

Table 2. Submission/Award Data for the FY17 BCRP* from Stage 1 Programmatic Review

Mechanism	Pre-Applications Received	Applications Invited (%)	Compliant Applications Received	Applications Recommended for Stage 2 Programmatic Review
Breakthrough Award – Funding Level 4	7	3 (42.9%)	2	0 (0%)
Era of Hope Scholar Award	n/a ⁺	n/a ⁺	8	0 (0%)
Innovator Award	17	3 (17.6%)	2	0 (0%)
Distinguished Investigator Award	9	1 (11.1%)	1	1 (100%)

⁺ n/a: not applicable; PIs submitting to the Era of Hope Scholar Award PA were required to submit a Letter of Intent (LOI).

THE TWO-TIER REVIEW SYSTEM

The USAMRMC developed a review model based on recommendations of the 1993 Institute of Medicine (IOM) of the National Academy of Sciences report, *Strategies for Managing the Breast Cancer Research Program: A Report to the Army Medical Research and Development Command*. The IOM report recommended a two-tier review process and concluded that the best course would be to establish a peer review system that reflects not only the traditional strengths of existing peer review systems, but also is tailored to accommodate program goals. The Command has adhered to this proven approach for evaluating competitive applications. An

application must be favorably reviewed by both levels of the two-tier review system to be funded.

THE FIRST TIER—Scientific Peer Review

Breakthrough Award Levels 3 and 4, Era of Hope Scholar Award, Innovator Award, and Distinguished Investigator Award applications were peer reviewed in February 2018 by three panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs.

Each peer review panel included a Chair, scientific reviewers, consumer reviewers, and a nonvoting Scientific Review Officer (SRO). The primary responsibility of the panelists was to review the technical merit of each application based upon the evaluation criteria specified in the relevant PA.

Individual Peer Review Panels

The Chair for each panel presided over the deliberations. Applications were discussed individually. The Chair called upon the assigned reviewers for an assessment of the merits of each application using the evaluation criteria published in the appropriate PA. Following a panel discussion, the Chair summarized the strengths and weaknesses of each application, and the panel members then rated the applications confidentially.

Application Scoring

Evaluation Criteria Scores (Breakthrough Award Levels 3 and 4): Panel members were asked to rate each peer review evaluation criterion as published in the appropriate PA. A scale of 1 to 10 was used, with 1 representing the lowest merit and 10 the highest merit. The main reasons for obtaining the criteria ratings were to (1) place emphasis on the published evaluation criteria and provide guidance to reviewers in determining an appropriate overall score, and (2) provide the applicant, the Programmatic Panel, and the Command with an informed measure of the quality regarding the strengths and weaknesses of each application. The evaluation criteria scores were not averaged or mathematically manipulated in any manner to connect them to the global or percentile scores.

Overall Score (Breakthrough Award Levels 3 and 4): To obtain an overall score, a range of 1.0 to 5.0 was used (1.0 representing the highest merit and 5.0 the lowest merit). Reviewer scoring was permitted in 0.1 increments. Panel member scores were averaged and rounded to arrive at a two-digit number (1.2, 1.9, 2.7, etc.). The following adjectival equivalents were used to guide reviewers: Outstanding (1.0–1.5), Excellent (1.6–2.0), Good (2.1–2.5), Fair (2.6–3.5), and Deficient (3.6–5.0).

In contrast to the typical technical merit review process, no criteria scores were assigned to the Era of Hope Scholar Award, Innovator Award, and Distinguished Investigator Award applications. Instead, reviewers were asked to address specific questions pertaining to the applicant's qualifications, accomplishments, research goals or ideas, and leadership skills. Each reviewer then voted confidentially on an overall level of enthusiasm (High, Medium, Low).

Summary Statements: The SRO on each panel was responsible for preparing a Summary Statement reporting the results of the peer review for each application. The Summary Statements included the applicants' abstracts, the evaluation criteria and overall scores, peer reviewers' written comments, and the essence of panel discussions. This document was used to report the peer review results to the Programmatic Panel. It is the policy of the USAMRMC to make Summary Statements available to each applicant when the review process has been completed.

THE SECOND TIER—Programmatic Review

Stage 1 Programmatic review was conducted in April 2018, by the FY17 Programmatic Panel, comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in breast cancer. Programmatic review is a comparison-based process that considers scientific evaluations across all disciplines and specialty areas. Programmatic Panel members do not automatically recommend funding applications that were highly rated in the technical merit review process; rather, they carefully scrutinize applications to allocate the limited funds available to support each of the award mechanisms as wisely as possible.

Programmatic review criteria published in the Breakthrough Award Levels 3 and 4 PA for Stage 1 were as follows: ratings and evaluations of the peer reviewers; relevance to the mission of the Defense Health Program (DHP) and FY17 BCRP; relative impact; program portfolio composition; and adherence to the intent of the award mechanism. For Stage 2 (*Funding Level 4 only*), the criteria included: understanding of barriers to overcome in the overarching challenge selected/identified; articulation of a realistic vision for transitioning the results of the project into a near-term clinical impact for individuals with, or at risk for, breast cancer; and capability to lead efforts to transform and revolutionize the clinical management and/or prevention of breast cancer.

Programmatic review criteria published in the Era of Hope Scholar Award, Innovator Award, and Distinguished Investigator Award PAs for Stage 1 were as follows: ratings and evaluations of the peer reviewers; relevance to the mission of the DHP and the FY17 BCRP; relative innovation; and adherence to the intent of the award mechanism. For Stage 2, the criteria included: understanding of barriers in breast cancer; articulation of a realistic vision with a high potential to impact breast cancer; and leadership capabilities to form partnerships and collaborations that will impact breast cancer.

After Stage 2 programmatic review, the Commanding General, USAMRMC, and the Director of the Defense Health Agency J9, Research and Development Directorate, will approve funding for the applications recommended during Stage I programmatic review.